

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 38147-0022WO	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2004/012730	International filing date (<i>day/month/year</i>) 26 April 2004 (26.04.2004)	Priority date (<i>day/month/year</i>) 25 April 2003 (25.04.2003)]	
International Patent Classification (IPC) or national classification and IPC ⁷ C12Q 1/68, C07H 21/04, A01N 43/04			
Applicant INTRADIGM CORPORATION			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 04 November 2005 (04.11.2005)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold;">Yolaine Cussac</div>
Telephone No. +41 22 338 70 80	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
PAUL M. BOOTH
HELLER EHRMAN WHITE & MCAULIFFE LLP
SUITE 300
1666 K STREET, NW
WASHINGTON, DC 20006-1228

PCT

REC'D 27 OCT 2005

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference

38147-0022WO

Date of mailing
(day/month/year)

25 OCT 2005

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US04/12730

International filing date (day/month/year)

26 April 2004 (26.04.2004)

Priority date (day/month/year)

25 April 2003 (25.04.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): C12Q 1/68; C07H 21/04; A01N 43/04 and US Cl.: 435/6; 536/24.5; 514/44

Applicant

INTRADIGM CORPORATION

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (703) 305-3230

Authorized officer

Janet L. Epps-Ford, Ph.D.

Telephone No. 571-272-1600

Janice Ford
for

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/12730

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☐ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☐ in computer readable form

c. time of filing/furnishing

☐ contained in international application as filed.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/12730

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 5,8-10 and 16

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____ are so unclear that no meaningful opinion could be formed (*specify*):

☒ the claims, or said claims Nos. 5,8-10 and 16 are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐

has not been furnished

☐

does not comply with the standard

the computer readable form

☐

has not been furnished

☐

does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US04/12730

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>1-4, 6-7, 11-15, 17-29</u>	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims <u>3, 6-7, 11-15, 17-29</u>	YES
	Claims <u>1-2 and 4</u>	NO
Industrial applicability (IA)	Claims <u>1-4, 6-7, 11-15, 17-29</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 3, 6-7, 11-15, and 17-29 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest or enable the use of dsRNA, comprising a loop structure, targeting the SARS virus for treating or preventing a coronavirus infection in a subject. Moreover, the prior art does not teach the use of PCR to detect a SARS virus, wherein the method comprises the use of a PCR primer that is not complementary to a SARS sequence.

Claims 1-2, and 4 lack an inventive step under PCT Article 33(3) as being obvious over Beach et al. in view of Drosten et al. Beach et al. teach a general method for RNA interference and further teaches that double stranded DNA which comprises a nucleotide sequence that hybridizes under stringent conditions to a gene of interest can be used to attenuate the expression of the target gene.

Drosten et al. describes the identification of a novel coronavirus that is associated with severe acute respiratory syndrome. On pages 1972-1973 Drosten et al. provides a genetic characterization of the novel coronavirus. Drosten et al. designates the particular regions of the sequence that code for the spike protein, and the non-structural proteins, among others, which appear necessary for the activity of the virus.

It would have been obvious to the ordinary skilled artisan to have designed a dsRNA targeting the coronavirus associated with SARS as described by Drosten et al. since the virus sequence is characterized by Drosten et al. and Beach et al. clearly describe the ability of the skilled artisan to describe dsRNA inhibitors of a targeting gene, wherein the sequence of the target gene is characterized. Moreover, it would have been obvious to target the particular regions which encode proteins that are involved in the functional activity of the virus, for example the spike protein encoding sequence.